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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,453	11/28/2003	James C. Peacock III	53233-00007	9909

48423 7590 04/21/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
04/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,453	PEACOCK, JAMES C.	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,9 and 11-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,9 and 11-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2009 has been entered.

2. Claims 2-6, 8, 9, and 11-46 are currently pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the disclosure for the limiting the inner diameter of the pores to be greater than about 1 micron.

5. Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the disclosure for the limitation "the fourth material located between the first material and the third material" (claim 29) while "the first material comprises a coating located on and in contact with the third material" (claim 17, from which claim 29 depends).

6. Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17, from which claim 29 depends, recites "the endolumenal stent comprises a scaffold constructed from a third material; the first material comprises a coating located on and in contact with the third material". There is insufficient support in the disclosure for how the first material and the third material can be separated by the third material (claim 29) while the first material is in contact with the third material (claim 17).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-11 and 16-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites in part "wherein said plurality of discrete particles are structurally co-deposited together with said first material on said

endolumenal surface and within each of the pores that are formed at least in part around the particles and thereby comprising a structurally co-deposited composite surface" in lines 8-11. It is unclear as to what Applicant is intending to claim, with particular attention drawn to the quoted limitation. For the purposes of examination, the Examiner is interpreting the limitation to claim a plurality of particles and a plurality of pores with at least one pore in each particle such that the particles are structurally co-deposited with the first material to form the pores.

Regarding claim 29, the claim language is indefinite. Claim 17, from which claim 29 depends, recites "the endolumenal stent comprises a scaffold constructed from a third material; the first material comprises a coating located on and in contact with the third material". It is unclear if the endolumenal stent comprises two scaffolds constructed from two different third materials and if the first material comprises two different coatings. For the purpose of examination, the limitation in claim 29 is being interpreted as a duplicate of that in claim 17 such that Applicant only intends to claim one scaffold constructed from a third material and the first material comprising one coating. Additionally, it is unclear how the first material and the third material can be separated by the third material (claim 29) while the first material is in contact with the third material (claim 17).

9. Claim 2 recites the limitation "said plurality of discrete particles" in line 8. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 32 recites the limitation "the first coating material". The claims from which claim 32 depend merely recite a coating material, not a *first* coating material. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102/103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 2-6, 12-31, 34-37, 39, and 43-46 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'Brien et al. (US 2005/0060021). Regarding claims 2-6, 12, 17, 18, 29, 34-37, 39, and 43, O'Brien et al. disclose a stent (Fig 2A) comprising a scaffold from a third material (20/60), an intermediate fourth material (22/62), a porous surface (24/64) comprising a first coating material (26) having a plurality of discrete pores (27, 28), and a second composite material comprising a plurality of particles, wherein each particle may be defined as a small portion of the second material located within each of the pores, or the volume of the second material entirely filling each pore. The second material is composed of a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). The pores comprise an inner diameter less than 1 micron (¶0036). The particle diameter may be defined as the inner diameter of the pore, and thus the particle diameter is less than 1 micron. The bioactive agent may comprise an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, and/or a growth factor (¶0061). The first coating material may be non-polymeric electrochemically deposited

material and the fourth material may be electroplated metal (¶0038, 0045). The pores are formed in the first coating material through an anodization process (¶0041).

Regarding claims 2 and 44, the claimed phrase, "structurally co-deposited" is being treated as a product by process limitation; that is, a product is formed by structurally co-depositing two materials together. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The endolumenal stent system of O'Brien et al. appears to be substantially the same product as claimed as shown above.

Regarding claim 17, the scaffold may be interpreted as comprising third material (20/60) and intermediate fourth material (22/62).

Regarding claims 13-16, the claimed phrase "wherein the pores are..." is being treated as a product by process limitation; that is, the pores are formed by laser cutting, photochemical etching, chemical etching, or sintering. Regarding claims 19-28, the claimed phrase "the non-polymeric material comprises an electrochemically deposited material" is being treated as a product by process limitation; that is, the non-polymeric material is formed by electrochemical deposition. Regarding claims 30 and 31, the claimed phrase "the fourth material comprises an electroplated metal" is being treated as a product by process limitation; that is, the fourth material is formed by electroplating. Regarding claim 45, the system comprising "a plurality of metal ions within the coating

environment, a plurality of discrete composite particles..., wherein the coating environment is adapted to co-deposit the metal from the metal ions into a coating material in combination with the composite particles onto the endolumenal stent surface to form a structurally co-deposited composite surface coating..." is being treated as a product by process limitation; that is, the stent coating is formed by co-depositing metal ions and composite particles. Regarding claim 46, the claimed phrase, "a coating environment with a coating precursor material, a plurality of composite particles located within the coating environment...wherein the coating environment is adapted to co-deposit the coating material from the precursor material in combination with the composite particles...so as to form a structurally co-deposited composite surface coating" is being treated as a product by process limitation; that is, the stent coating is formed by co-depositing a coating material, formed from a precursor material, and composite particles. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The endolumenal stent system of O'Brien et al. appears to be substantially the same product as claimed as shown above.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 2 above. O'Brien et al. disclose the invention substantially as claimed as shown above. However, O'Brien et al. do not disclose the pores comprise an inner diameter of about 1 to 2 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the pores comprised an inner diameter that is greater than about 1 micron and less than about 2 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 2 above, in view of Lye et al. (US 2004/0148015). O'Brien disclose the invention substantially as claimed as shown above including a stent (Fig 2A) with a porous surface (24) comprising a first coating material (26) having a plurality of discrete pores (27, 28), and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). However, O'Brien et al. do not disclose the first material is inherently porous. Lye et al. disclose a similar device including a stent with a porous surface. Lye et al.

teach porous materials are commonly used in medical implants as matrices for the retention of therapeutic agents. Such materials include ceramics and sintered metal powders (¶0003). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the first material included an inherently porous material to simplify the manufacturing process by eliminating the step of forming the pores by anodization.

16. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 29 above, in view of Gertner et al. (US 2003/0060873). Regarding claim 32, O'Brien et al. disclose the invention substantially as claimed as shown above including an intermediate fourth material (22/62) between the first material and the third material. However, O'Brien et al. do not disclose a fifth material between the fourth material and the first coating material. Gertner et al. teach a fourth material may be formed between the stent, or third material, and the coating, or second material, and a fifth material may be formed between the fourth material and the coating, or second material, since a plurality of layers may be formed with coating layers between metallic layers (¶0063). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the stent system comprised an additional fifth material between the fourth material and the first coating material. The additional layers may provide an additional layer of pores to provide a greater amount of bioactive agent to improve the drug delivering capacity of the device or may provide additional structural support for the device to improve the radial strength of the endolumenal stent.

Regarding claim 33, the limitations "the fourth material comprises electoplated metal" and "the fifth material comprises a first layer of an electrolessly electrochemically deposited composite material" and "the coating material comprises a second layer of an electrolessly electrochemically deposited composite material" are being treated as product by process limitations; that is, the fourth material is formed by electroplating, and the fifth material and coating material are formed by electroless electrochemical deposition. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The endolumenal stent system of O'Brien et al. appears to be substantially the same product as claimed as shown above.

17. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 2 above, in view of Wang et al. (US 2007/0037739). O'Brien et al. disclose the invention substantially as claimed including a stent comprising a scaffold from a third material (20), a porous surface (24) comprising a first material (26) and having a plurality of pores (27, 28), and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible material (¶0060). Furthermore, the bioactive agent may comprise an anti-restenosis agent, anti-inflammatory agent, anti-proliferative agent, or growth factor (¶0061). However, O'Brien et al. do not disclose the bioactive agent may comprise des-aspartate angiotensin 1.

Wang et al. disclose compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 (¶0040, 0253-0261) which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis (¶0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the bioactive agent may also comprise des-aspartate angiotensin 1. Thus, the marketability of the device would increase and the stent may be more effective by effectively reducing restenosis.

18. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 2 above. O'Brien et al. disclose the second composite material located within the pores is composed of a bioerodible polymer material in combination with a bioactive agent (¶0060). However, O'Brien et al. do not disclose the ratio of bioactive material to bioerodible material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the second composite material was formed with a ratio of bioactive material to bioerodible material to be at least 0.5:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

19. Applicant's arguments with respect to claims 2-6, 8, 9, and 11-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
April 10, 2009

/K. M. D./
Examiner, Art Unit 3734